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EXAMINER

CHIN, C

ART UNIT	PAPER NUMBER
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1641

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/185,318

Applicant(s)

Reichert et al

Examiner

Chris Chin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 5, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-34 is/are pending in the application.
- 4a) Of the above, claim(s) 30-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

Election/Restriction

1. Newly submitted claims 30-34 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

New claims 30-34 recite a method that utilizes a step-gradient waveguide that is not required for the originally elected method of claims 25-29. The step-gradient waveguide would require an additional search and thus would have been restricted from the originally elected claims 25-29.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 30-34 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 U.S.C. § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

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3. Claims 25, 26, 28, and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Squirrell.

Squirrell (U.S. Patent 5,750,337) discloses a method for the detection, identification, and/or quantification of plant or animal RNA or DNA and a detector apparatus for performing said method. The method uses total internal reflection fluorescence (TIRF) to measure hybridization of analyte RNA or DNA with RNA or DNA that is associated with an evanescent wave detector waveguide. Evanescent wave detectors exploit the TIRF phenomenon to provide a sensitive method for detecting reactions at the surface of waveguides. The waveguide may take various forms but typically will be a prism, slab, or fiber. The reaction to be used to measure the target molecule may be monitored through measuring the fluorescence changes on binding or desorption of fluorescent species or by the generation of fluorescent species by enzymic or chemical means. The basic method comprises providing oligonucleotides specific for the target RNA or DNA immobilized on the surface of an evanescent waveguide, exposing the immobilized oligonucleotides to a sample containing analyte RNA or DNA under conditions whereby the analyte RNA or DNA having a complimentary sequence hybridizes to the immobilized oligonucleotides on the waveguide, contacting the waveguide with a fluorescently detectable agent that becomes bound to the hybridized product, and measuring the fluorescently detectable agent bound to the waveguide (col. 1, line 6, to col. 2, line 17). The fluorescently detectable agent is a fluorescently detectable complementary oligonucleotide (col. 3, lines 37-46). Figure 1 shows an embodiment of an apparatus for carrying out the disclosed method. The apparatus comprises a

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6 watt light source, various lenses and filters, an oligonucleotide bearing waveguide, and a detector (col. 7, lines 13-30). The waveguide is an optic fiber and is treated with reagents to silanize the surface of the optic fiber and further treated with glutaraldehyde for covalent attachment of oligonucleotides having aminoterminals (col. 7, lines 44-55).

On the waveguide of Squirrell, the glutaraldehyde reads on the "first coating" in the instant claims since it provides the required function of coupling oligonucleotides to the waveguide surface.

4. Claims 25, 26, 28, and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Bouma et al.

Bouma et al (U.S. Patent 5,585,242) discloses an apparatus and method for detecting the presence and concentration of amplified target nucleic acids by total internal reflection. The disclosed method comprises providing a reaction vessel having disposed therein a total internal reflection (TIR) element, a plurality of initiator sequence sets and reagents for producing amplification of target nucleic acid present in a sample, label means coupled to a fluorophore, and capture means for bringing said fluorophore within the penetration depth of the TIR element, wherein the label means and capture means is specific for the target nucleic acid; producing an evanescent wave in the TIR element; reacting the sample and reagents in the reaction vessel; capturing said label means with the penetration depth as a function of the presence or amount of target nucleic acid; and detecting a change in fluorescence (col. 3, lines 25-62). Figure shows the

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apparatus for the carrying out the disclosed method. The TIR element can be of any number of optically transparent materials, such as glass, quartz, and transparent polymers (col. 6, lines 61-66, and col. 7). The surface of the TIR element is modified to include a plurality of coupling sites for attachment of capture means for bringing fluorophore within the penetration depth (col. 8, lines 21-67). Alternatively, the capture means is coupled to the TIR element via a spacer arm linker, such as avidin (col. 13, lines 8-27).

On the TIR element of Bouma et al, the coupling sites and/or spacer arm linker are considered to read on the “first coating” in the instant claims since it provides the required function of coupling oligonucleotides to the waveguide surface.

Claim Rejections - 35 U.S.C. § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Squirrell in view of Wybourne et al.

See above for the teachings of Squirrell.

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The method of Squirrell differs from the instant invention in failing to teach the use of biotin as means to immobilize oligonucleotides to the waveguide surface.

Wybourne et al (U.S. Patent 5,465,151) discloses chemical and biochemical biosensors. The disclosed biosensors contain sensor elements that exploit total internal reflection of electromagnetic radiation in a waveguide. The waveguide can be any non-fluid substance that exhibits a refractive index to the electromagnetic radiation to be passed through the waveguide. Waveguide substances can include, but are not limited to, a wide variety of polymeric materials and siliceous materials (col. 3, line 60, to col. 4, line 66). The waveguide surfaces are functionalized by exposing the surface to a nitrogenic functionalizing reagent in the presence of a reaction-energy source such as photons, electrons, or heat. The functionalizing reagent provides a means by which a specific binding reagent, such as a nucleic acid, can be immobilized onto the waveguide surface (col. 5, lines 1-67). The waveguide surface can be biotinylated in a one or two-stage reaction, followed by treatment of the biotinylated surface with a derivatized avidin or streptavidin. The avidin or streptavidin are thus used as bridging units for subsequent attachment of other biomolecules to the waveguide surface (col. 22, lines 60-67). Example 7 discloses functionalizing a polymer surface (i.e. a waveguide surface) with biotin groups. The biotinylated surfaces can be further reacted so as to attach biomolecules to the surface through biotin-binding proteins such as avidin.

It would have been obvious to one of ordinary skill in the art to use an avidin-biotin system, as taught by Wybourne et al, as an alternative means to immobilize the oligonucleotides

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onto the waveguide in the method of Squirrell because Wybourne et al shows it to be well known and conventional in the art to use avidin-biotin systems to immobilize oligonucleotides onto a waveguide such as the waveguide used in the method of Squirrell. Furthermore, due to the high binding affinity of avidin for biotin, the use of avidin-biotin systems provide for a highly accurate and effective way to immobilize oligonucleotides to a waveguide surface.

7. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bouma et al in view of Wybourne et al.

See above for the teachings of Bouma et al.

While Bouma et al discloses the use of avidin as a spacer linker arm to immobilize a capture means (i.e. an oligonucleotide) to the TIR element, Bouma et al fails to specifically teach the use of an avidin-biotin system to immobilize the oligonucleotides onto the surface of the TIR waveguide element.

See above for the teachings of Wybourne et al.

It would have been obvious to one of ordinary skill in the art to use an avidin-biotin system, as taught by Wybourne et al, as an alternative means to immobilize the oligonucleotides onto the waveguide in the method of Bouma et al because Bouma et al teaches the use of avidin as a means to immobilize a capture means onto a waveguide surface and Wybourne et al shows it to be well known and conventional in the art to use avidin-biotin systems to immobilize oligonucleotides onto a waveguide such as the waveguide used in the method of Bouma et al.

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Furthermore, due to the high binding affinity of avidin for biotin, the use of avidin-biotin systems provide for a highly accurate and effective way to immobilize oligonucleotides to a waveguide surface.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent 5,494,798 discloses a fiber optic sensor for performing nucleic acid binding assays.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 9:30 am to 7:00 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

cchin/cc
August 25, 2001



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/641